

REMARKS**1. Preliminary Remarks****a. Status of the Claims**

Claims 31, 32, and 39-42 are pending in this application. Claims 31 and 39 are allowed, while claims 32 and 40-42 are rejected. Claims 41 and 42 are amended. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 31, 32, and 39-42 will be pending and under active consideration.

b. Amendments to the Claims

Claims 41 and 42 are amended to recite probes of 50-120, and 18-24 or 50-120 nucleotides in length, respectively, support for which can be found at paragraphs 0017 and 0028 of U.S. Patent Application No. 10/707,147, filed on November 24, 2003 as originally filed (the “Priority Application”), to which the instant application claims priority and of which the contents have been incorporated by reference in the instant application. Because the amended claims find support in the original specification, Applicant submits that no new matter has been added.

c. Priority

On pages 2 and 3 of the Office Action, the Examiner asserts that the earliest effective filing date of the claims is February 16, 2004. The Examiner basis this conclusion on an assertion that the Priority Application does not provide sufficient written description support for DNAs encoding instant SEQ ID NOS: 6527 or 15, complements thereof, or probes of 16-140 nucleotides including these sequences. Applicant respectfully disagrees in view of amended claims 41 and 42 and the following remarks.

First, Applicant submits that the Examiner has already acknowledged that the earliest effective filing date of the subject matter of claims 31, 32, 39, and 40 is November 24, 2003. *See* the Office Action mailed on January 26, 2010 at page 3, paragraph 2 (“... for purposes of this examination the earliest effective filing date of the instant claims continues to be that of 10/707147: 11/24/2003”) (original emphasis). Instant claims 31, 32, 39, and 40 remain unchanged since the Examiner’s acknowledgement of the November 24, 2003 effective filing date for these claims.

Second, Applicant submits that disclosure of a RNA sequence necessarily discloses a DNA that encodes the RNA, as well as the complement. It is well-known in the art of molecular biology that RNAs are encoded by DNAs, and that DNAs are double-stranded, such that the sequence of one strand has a complementary sequence on the other strand. Accordingly, the disclosure of SEQ

ID NOs: 303 and 169 in the Priority Application necessarily discloses equivalent RNA and DNA sequences, as well as their complements. Vectors containing these sequences are disclosed at paragraph 0013 of the Priority Application. The subject matter of claims 31, 32, 39, and 40 therefore finds sufficient written description support in the Priority Application, and should be accorded the filing date of the Priority Application.

Third, amended claims 41 and 42 relate to probes having lengths of 50-120, and 18-24 or 50-120 nucleotides, respectively, and including the nucleic acids of claims 31 and 32, respectively. Support for such probes find support in the Priority Application at paragraphs 0017 and 0028 of the Priority Application, and SEQ ID NOs: 303 and 169 of the Instant Application. Accordingly, the subject matter of claims 41 and 42 should likewise be accorded the filing date of the Priority Application, which is November 24, 2003.

2. Patentability Remarks.

a. 35 U.S.C. § 112, first paragraph—new matter

On pages 4-6 of the Office Action, the Examiner rejects claims 41 and 42 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement on grounds that they include new matter. The Examiner asserts that the length limitation of 16-140 nucleotides is not supported by the instant specification. In view of amended claims 41 and 42, Applicant respectfully disagrees. Amended claims 41 and 42 relate to probes of 50-120, and 18-24 or 50-120 nucleotides in length, respectively. Applicant submits that this limitation finds written description support in the Priority Application, as discussed above. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 41 and 42 under 35 U.S.C. § 112, first paragraph.

b. 35 U.S.C. § 102

(1) Tuschl

On pages 6-13 of the Office Action, the Examiner rejects claims 32, 40, and 42 under 35 U.S.C. § 102(e) as allegedly being anticipated by WO 03/029459 (“Tuschl” hereafter). The Examiner asserts that Tuschl discloses mouse miR-151 (having SEQ ID NO: 179), which is a 22-mer that differs from instant SEQ ID NO: 15 by two nucleotides, as well as 80%, 90%, 95%, and 99% variants thereof. This is a large genus of sequences that allegedly includes the subject matter of instant claim 32. The main issue is whether the genus of miR-151 variants disclosed by Tuschl is sufficiently limited or well-delineated so as to anticipate the subject matter of instant claims 32, 40

and 42. Applicant submits that it is not, in view of guidelines set forth in the MPEP and relevant case law.

When it is necessary to arrive at claimed subject matter from a prior art reference by selecting portions of the prior art from various sections and combine them, anticipation of a species by a genus can be found only, “if the classes [are] sufficiently limited or well delineated.”¹ To arrive at the genus of 80%, 90%, 95%, and 99% variants of miR-151 cited by the Examiner, the Examiner had to select a particular sequence from one of four tables spanning twelve pages and disclosing 160 different sequences, and combine that sequence with the disclosure of the different percent variants in a different portion of Tuschl. Applicant previously established that Tuschl in its entirety discloses nearly 200 million nucleic acids.² Even if one were to start with only the genus of miR-151-related nucleic acids, this subgenus of Tuschl includes 636,241 different nucleic acids.³ In comparison, genera of 70 salts,⁴ 105 compounds,⁵ and 20 compounds⁶ have been held to anticipate a species contained within each of these genera. In contrast, a genus of 230,000 compounds has been held to be insufficiently limited or well delineated so as to anticipate a species contained within the genus.⁷ Applicant submits that in view of the genus cited by the Examiner encompassing 636,241 different nucleic acids (or nearly three times 230,000), the genus of miR-151-related nucleic acids from Tuschl is also insufficiently limited or well delineated so as to anticipate the subject matter of claims 32, 40, and 42. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 32, 40, and 42 under 35 U.S.C. § 102(e) over Tuschl.

¹ See *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (“In each case [of anticipation], to arrive at the claimed subject matter, it was necessary to select portions of that subject matter from various sections of the reference disclosure and combine them, e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound. Even in those cases, if the classes were sufficiently limited or well delineated, anticipation was found”) and see MPEP § 2133.02.

² See Applicant’s Office Action Reply submitted April 17, 2010 at page 5.

³ 80% variants of a 22-mer can differ at four positions without replacement and without regard to order, and each position can be any one of the three other bases. Therefore, the genus of 80% includes $22! / ((22-4)!4!) * 3^4 = 592,515$. By similar calculations, the genus of 80%, 90%, 95%, and 99% variants can differ by between 0 and 3 bases, and the total number of these variants reaches 636,241 different nucleic acids.

⁴ *In re Sivaramakrishnan*, 213 USPQ 441.

⁵ *In re Schaumann*, 197 USPQ 5.

⁶ *In re Petering*, 133 USPQ 275.

⁷ *In re Arkley*, 172 USPQ 524.

(2) Croce

On page 13 of the Office Action, the Examiner rejects claims 32, 40, and 42 under 35 U.S.C. § 102(e) as allegedly being anticipated by US 2006/0105360 (“Croce” hereafter). The Examiner asserts that subject matter of claims 32, 40, and 42 is disclosed in a priority application for Croce that has a filing date of February 9, 2004. As established above, however, the earliest effective filing date of the subject matter of claims 32, 40, and 42 is November 24, 2003, which precedes the earliest cited filing date of Croce. Accordingly, Croce is not prior art under 35 U.S.C. § 102(e). In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 32, 40, and 42 under 35 U.S.C. § 102(e) over Croce.

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

POLSONELLI SHUGHART PC

Dated: August 23, 2010

On behalf of: Teddy C. Scott, Jr., Ph.D.
Registration No. 53,573

By: /Ron Galant/
Ron Galant, Ph.D.
Registration No. 60,558
Customer No. 37808

POLSINELLI SHUGHART PC
161 N. Clark St., Ste. 4200
Chicago, IL 60601
312.819.1900 (main)
312.873.2913 (E-fax)
312.873.3613 (direct)